

Remarks:

The September 20, 2005 Official Action has been carefully considered. In view of the amendment submitted herewith and these remarks, favorable reconsideration and allowance of this application are respectfully requested.

At the outset, it is noted that a shortened statutory response period of three (3) months was set in the September 20, 2005 Official Action. The initial due date for response, therefore, was December 20, 2005. A petition for a two (2) month extension of the response period is presented with this amendment and request for reconsideration, which is being filed before the expiration of the two (2) month extension period.

Claims 13-15, 17-22 and 27 stand rejected in the September 20, 2005 Official Action for allegedly failing to satisfy the enablement and written description requirements of 35 U.S.C. §112.

In support of the rejection based on alleged inadequate enablement, the examiner states that the pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. In re Fisher, 166 U.S.P.Q. 18 (C.C.P.A. 1970) is cited by the examiner in support of this proposition. The examiner further contends in this regard that applicants have not shown the claim compounds to be effective to treat HCV, and that one skilled in the art would not be able to use the compounds effectively without undue experimentation.

In support of the rejection based on alleged insufficient written description, the examiner asserts that the specification does not teach how to use the claimed compounds.

Turning to claims 1-12, these claims are objected to in the September 20, 2005 Official Action to the extent they read on non-elected subject matter. The examiner stated, however, that cancellation of the non-elected subject matter will render

claims 1-12 allowable.

The foregoing objection and rejections constitute all of the grounds set forth in the September 20, 2005 Official Action for refusing the present application.

Applicants, through their undersigned attorney, requested a telephone interview with Examiner Covington, which was conducted on February 7, 2006. The courtesy extended to applicants' attorney by granting the interview request is appreciated.

The principal purpose of the interview was to obtain clarification of the scope of the subject matter required to be canceled from claims 1-12 in order to obtain their allowance. After reviewing the sixteen (16)-way restriction requirement set forth in the preceding official action, it was agreed that if claims 1-12 were amended to delete all references to benzofuran compounds having any heterocyclic substituents, then claims 1-12 would be allowed. The allowability of claims 1-12, if thus amended, is consistent with the examiner's determination that claims 1-12, with no other heterocyclic substituents and including pharmaceutical salts and pharmaceutical compositions thereof, constitute a patentable invention separate from the compounds claimed in Groups II through XII, all of which are drawn to benzofuran compounds that include heterocyclic substituents.

It was also agreed that if claims 1-12 were amended in the manner described above, claims 13-15, which constitute Group XIII, and claims 17-22 and 27, which constitute Group XV, would likewise be allowable. The allowability of claims 13-15, as predicated on the agreed upon amendment of claims 1-12, is in keeping with the examiner's indication that the subject matter of Group I, including the benzofuran compounds of formula I with no heterocyclic substituents, includes pharmaceutical compositions. Furthermore, the allowability of claims 17-22 and 27, as predicated on the agreed upon amendment of claims 1-12,

is in keeping with the examiner's acknowledgment of the appropriateness of rejoinder of restricted process of use claims with allowed product claims where, as here, the process of use claims depend from or otherwise include all the limitations of the allowed product claims. See §821.04 of the Manual of Patent Examining Procedure, cited at page 8 of the September 20, 2005 Official Action.

The omission of any reference to the restriction requirement in the body of the September 20, 2005 Official Action (i.e. pages 2-6 thereof) was also discussed during the February 7, 2006 telephone interview. In this connection, it was agreed that upon entry of the proposed amendment of claims 1-12, the restriction requirement would be made final in the next succeeding official action. Accordingly, the prohibition against double patenting rejections provided in 35 U.S.C. § 121 would apply with respect to any divisional applications subsequently filed by applicants.

In accordance with the present amendment, claims 1-12 have been amended in the manner described above. Specifically, all recitations pertaining to heterocyclic substituents have been deleted from claims 1-12. Also, claims 16 and 23-26 which are withdrawn from consideration, as indicated on the Official Action Summary page of the September 20, 2005 Official Action, have been canceled.

As a result of the present amendment, the 35 U.S.C. § 112, first paragraph rejections of claims 13-15, 17-22 and 27 are rendered moot. Nevertheless, applicants respectfully traverse these grounds of rejection, because they are unfounded.

The law is well-settled that whenever a rejection based on inadequacy of enablement is made, it is incumbent upon the Patent and Trademark Office (PTO) to explain why the truth or accuracy of the applicants' disclosure is doubted, and to back up any such doubt with acceptable evidence or reasoning which is

inconsistent with the contested disclosure. In re Marzocchi, 169 U.S.P.Q. 367 (C.C.P.A. 1971). A properly supported showing that applicants' disclosure entails undue experimentation is part of the PTO's initial burden under §112, first paragraph. In re Angstadt, 190 U.S.P.Q. 214 (C.C.P.A. 1976).

In the present case, applicants' specification clearly satisfies the "how to make" and "how to use" requirements of 35 U.S.C. §112.

Included in the present specification are fifty-one (51) working examples which describe the preparation of diverse compounds falling within the scope of the structural formula shown in claim 1. These examples enable the synthesis of compounds with and without heterocyclic substituents. In addition, there are over four hundred fifty (450) examples of compounds, including certain pharmaceutically acceptable salts thereof, that were actually made following the teachings of the present specification, as evidenced by the spectral data provided for most of those compounds. Biological activity data are provided for most of the exemplified compounds, as well.

The specification also gives detailed guidance concerning the preparation of pharmaceutical compositions comprising the benzofuran compounds of the invention, the appropriate amount of the active agent to be administered, as well as suitable routes of administration. See pages 23-25 of the present specification.

As for the examiner's contention that applicants' disclosure of utility is inadequate, this position is devoid of any supporting evidence or reasoning as required by the relevant case law. For example, in Ex parte Bhide, 42 U.S.P.Q. 2nd 1441 (PTO Bd. Apps. 1996), involving a rejection of claims to compounds and methods for inhibiting farnesyl protein transferase, as a means for treating cancer, the Board stated:

"A specification which contains a statement of the manner and process of using the invention in terms which correspond in scope to those used in defining the subject matter sought to be patented must be taken as in compliance with the "how to use" requirement of the first paragraph of 35 U.S.C. §112 unless there is a reason to doubt the objective truth of the statement" [emphasis in original].

In Bhide, there was evidence of record tending to show that, contrary to what was recited in the claims, Bhide's substituted tetrapeptides possessed the disclosed utility only when the fourth amino acid position was a cysteine. There is no comparable evidence of record in the present case that serves to support the examiners' doubt about applicants' disclosure of utility. The Tan et al. reference cited by the examiner plainly fails to contradict applicants' disclosure of utility for the compositions and methods claimed in claims 13-15, 17-22 and 27. Rather, Tan et al. establishes that there is currently available both the research tools and the knowledge base (i.e. understanding of the HCV replication cycle and the key enzymes involved) that are needed to identify and develop anti-HCV agents.

In re Fisher, supra, which is cited by the examiner in support of the inadequate enablement rejection of claims 13-15, 17-22 and 27, is readily distinguishable from the present case on its facts. In Fisher, the court disallowed a claim to an ACTH preparation including an open-ended recitation of ACTH potency, i.e. "at least one International Unit of ACTH per milligram", in view of the limited disclosure of ACTH potencies provided in the specification, which were only in the range of 1.11 to 2.30 IUs of ACTH per milligram. In the present case, by

contrast, the scope of applicants' claims is not open-ended, but is clearly defined and unquestionably warranted in view of the numerous representative examples provided in the present specification.

It is also noteworthy in this regard that the PTO has issued many patents claiming compounds and methods for the treatment of HCV. See, for example, U.S. Patents Nos. 6,803,374, 6,809,101 and 6,869,964. The claims of these patents encompass compounds of widely diverse structural formulas, including various aliphatic, cycloaliphatic, aromatic and heterocyclic substituents. None of these patents provides data evidencing "functional treatment" or "correlation to treatment in humans". According to the examiner, it is the lack of such data that renders applicants' specification deficient under 35 U.S.C. §112, first paragraph. See page 4 of the September 20, 2005 Official Action. The issuance of the aforementioned patents shows beyond doubt, however, that such data is not a prerequisite of patentability.

In summary, all that the examiner has done in this case is offer conclusory statements regarding the unpredictability of treating HCV. Under such circumstances, applicants cannot be required to substantiate their presumptively correct disclosure to avoid an enablement rejection under 35 U.S.C. §112. Cf. In re Brana, 34 U.S.P.Q. 2nd 1436 (Fed. Cir. 1995).

Furthermore, notwithstanding the examiner's assertion to the contrary, claims 13-15, 17-22 and 27 fully comply with the written description requirement of 35 U.S.C. §112, first paragraph.

The relevant inquiry in determining compliance with the written description requirement of 35 U.S.C. §112, is whether the specification in question reasonably conveys to a person having ordinary skill in the relevant art that applicants, at

the time their application was filed, had possession of the claimed subject matter. In re Kaslow, 217 U.S.P.Q. 1089 (Fed. Cir. 1983). Moreover, the examiner has the initial burden of presenting evidence or reasons why a person of ordinary skill in the art would not recognize in applicants' specification disclosure a description of the invention defined by the claims. Ex parte Sorenson, 3 U.S.P.Q. 2nd 1462 (Bd. Pat. Apps. 1987).

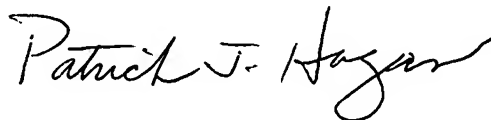
The factual inadequacy of the examiner's position in support of this rejection is quite evident, considering that in the present case applicants have prepared hundreds of compounds exhibiting biological activity against HCV, and have provided detailed guidance regarding how to use the compounds of the invention in the treatment of HCV. In view of such detailed disclosure, the conclusion is inescapable that applicants were in possession of the subject matter claimed in claims 13-15, 17-22 and 27 at the time the present application was filed. For his part, the examiner cited no evidence that would warrant a contrary conclusion, and thus failed to meet the PTO's burden of proof as to the adequacy of the written description of applicants' invention.

For the above-stated reasons, the rejections of claims 13-15, 17-22 and 27 for alleged failure to satisfy the enablement and written description requirements of 35 U.S.C. §112 are untenable and should, therefore, be withdrawn.

In view of the amendment submitted herewith and the foregoing remarks, it is respectfully urged that the objection and rejections set forth in the September 20, 2005 Official Action be withdrawn and that this application be passed to issue, and such action is earnestly solicited.

Respectfully submitted,

DANN, DORFMAN, HERRELL & SKILLMAN
A Professional Corporation
Attorneys for Applicant(s)

A handwritten signature in cursive script, reading "Patrick J. Hagan".

By

Patrick J. Hagan
PTO Registration No. 27,643

Telephone: (215) 563-4100
Facsimile: (215) 563-4044